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APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE 09/938,013 08/24/2001 Khue Vu Nguyen 9877 EXAMINER 06/04/2004 Dr. KHUE VU NGUYEN GOLDBERG, JEANINE ANNE 2828 University Avenue, Apt # 303 ART UNIT PAPER NUMBER SAN DIEGO, CA 92104 1634

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

1	Application No.	Applicant(s)
Office Action Summary	09/938,013	NGUYEN ET AL.
	Examiner	Art Unit
	Jeanine A Goldberg	1634
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
 1) Responsive to communication(s) filed on 10/8/03.; 12/9/03; 5/28/04. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 		
Disposition of Claims		
 4) Claim(s) 1 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 		
Application Papers		
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

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DETAILED ACTION

1. This action is in response to the papers filed October 6, 2003; December 19, 2003; May 26, 2003. Currently, claim 1 is pending.

2. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

- 3. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
- 4. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

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If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

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If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

- 5. Any objections and rejections not reiterated below are hereby withdrawn.
- 6. This action contains new grounds or rejection necessitated by the amendments to the claim.

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Maintained Rejections

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Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

- 8. The disclosure is objected to because of the following informalities.
- A) Page 1, line 15 recites "in cells ans tissues." It is presumed that the passage should read "in cells and tissues."

Appropriate correction is required.

Response to Arguments

The response traverses the rejection. The response asserts the appropriate corrections were made. This argument has been reviewed but is not convincing because the specification has not been amended in accordance with the rules.

Applicant's attention is direct to MPEP 714 for clarification about how to make amendments to the specification. Thus for the reasons above and those already of record, the rejection is maintained.

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New Matter

9. The amendment filed January 7, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

On January 7, 2002, Applicant's filed a sequence listing with 3 sequences to be entered into the case. Each of these sequences do not appear to be originally filed in the application and appear to constitute new matter. In a letter dated January 9, 2003, Applicants indicate that SEQ ID NO: 1-3 are probes 1-3. The response asserts that probes 1-2 are portions of exons 7-8 of the SMN gene. The examiner acknowledges that this assertion is correct, however, these sequences were not present in the originally filed application. The sequence of the exons 7-8 of the SMN gene were known at the time the invention was made, however, the exact sequence of probes 1-2 were not taught in the instant specification at the time the invention was made. The response attempts to point to support by identifying specific excerpts from the specification which discuss the SMN gene taught by Lefebvre. This disclosure does not provide the sequence of the probes claimed in the instant application. The probes 1-2 are not the full length exons 7-8, but rather portions of exons 7-8. Therefore, the specific sequences were not disclosed at the time the invention was made. The response filed January 9, 2003, clearly states, "the sequence of probes 1 and 2 were specified but not listed in the application because they are portions of the whole

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sequences of exons 7 and 8 respectively, already listed in the reference publication by Lefebvre et al., Ref. #16 stated in the reference list of the application."

As provided in MPEP 608.01 (p), "An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, Ex parte Schwarze, 151 USPQ 426 (Bd. App. 1966)." Moreover, "Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973)." Therefore, the instant specification does not appear to include a proper incorporation by reference. Thus, the essential subject matter may not be added to the instant specification.

Similarly, SEQ ID NO: 3 (probe 3) is not disclosed in the instant specification. While the sequence may be present in the art, this is not disclosure in the instant application.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

The response traverses the rejection. The response filed December 9, 2003 asserts that probe 1, 2, 3 are designed by particular primers. For example, the response asserts that probe 1 is formed from oligonucleotide (g) and (h). Applicant's point to the sequence of Lefebvre for support for the entire probe. It is noted that the sequence of each of these primers are provided in the specification on page 8, for example. However the intervening sequence is not provided in the specification. It is

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not clear from the specification that Lefebvre was incorporated by reference and the entire exon 7/8 sequences are not provided in the specification. Upon careful consideration, the examiner believes that the probes may be described in alternative language such that the probe was formed by PCR products of SEQ ID NO: 10 and 11, for example (see page 9, lines 11-13). The language on page 9 states, "the nucleotide probes so obtained (probes 1, 2, and 3 directed at exons 7 and 8 of the SMN and HUMEF1AB genes respectively) were then labeled withusing the previously synthesized oligonucleotides (d,g,h,i for the probes 1 and 2 and e, f for the probe 3)." This however does not provide the sequence between the two primers which was used to form the probe. Therefore, since the specification lacks an incorporation by reference and the intervening sequence, probe 1, 2, 3 constitutes new matter. With respect to probe 3, there is no discussion or disclosure in the instant specification of the HUMEF1AB sequence. Although the response argues that based upon such information available to persons in the field of molecular biology would know exactly that the sequence fragment from 672-723 of HUMEF1AB gene is to be amplified, this is not the standard applied to the requirement for new matter. New matter requires the specification to provide support or disclosure of the subject matter. Like the SMN gene, HUMEF1AB was not incorporated by reference or disclosed in the instant specification. The response argues the fact that the whole sequences of the exons 7 and 8 of the SMN gene are well known. This argument has been reviewed but is not convincing because the specification has not disclosed or taught the sequence of the probes. As noted above, the examiner believes that a claim may be constructed that does not

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require probe 1, 2, 3, but rather relies on the disclosure of the particular primers for support for a probe. Thus for the reasons above and those already of record, the rejection is maintained.

New Grounds of Rejection Necessitated by Amendment Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- A) Claim 1 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited. Also, the examiner has taken time to draft a set of claims which appear to better reflect applicant's invention in appropriate format. It is noted that this claim set does not appear to be allowable for the reasons given below, however, the claim is in better technical format than the previously submitted claim. In the event that the applicant wishes to enter the claim after final, the rejections below will be appropriate.

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- 1. A quantitative method for diagnosis of spinal muscular atrophy (SMA) comprising:
- a) obtaining human samples containing mRNA from patients suspected of having SMA and control patients
- b) reverse transcribing mRNA using primers consisting of SEQ ID NO: 4 and SEQ ID NO: 5 for the synthesis of cDNA from the mRNA of survival motor neuron (SMN) and human elongation factor 1-alpha (HUMEF1AB)
- c) amplifying by PCR using primers consisting of SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 and SEQ ID NO: 9
 - d) hybridizing the PCR products with labeled probes wherein the probes are generated by PCR amplification of SEQ ID NO:

10 and 11 for exon 7; SEQ ID NO: 12 and 7 for exon 8 and; SEQ ID NO: 8 and 9 for HUMEF1AB

EL IMD

- e) quantifying the amount of label in both the patients and the controls wherein ****(a quantitative value greater than the control)*** is indicative of SMA.
- A) The Claim 1 is indefinite because the claim appears to contain two distinct methods within the same claim. It is unclear whether the claim requires both steps 4 and 5. This does not make sense that an artisan would perform a radioactive labeling method and a biotin labeling method in the same protocol. Claim 1 is indefinite because the method lacks positive process steps which are required and a complete method. The claims do not provide any method steps for quantitatively measuring specific mRNA. Moreover, there is no final step to the method which completes the method. "The first copies of cDNA" lacks proper antecedent basis. The claim further contains parentheticals which are unclear whether they are intended to limit the claim or whether they are not limitations of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jong et al. (J. of the Neurological Sciences, Vol. 173, pages 147-153, February 2000) and Lefebvre et al. (Cell, Vol. 80, pages 155-165, January 13, 1995) and Feuerstein et al. (US Pat. 5,635,351, June 3, 1997) and Powell (PCR Protocols, A guide to Methods and Applications, page 237-243, 1990) and Gruber et al. (Histochem Cell Biol. Vol. 107, pages 411-416, 1997) and Bruce (Am J. Respir. Cell Mol. Biol. Vol. 20, pages 228-236, 1999) and in further view of Lefebvre et al. (Genbank Accession Number U438836, May 16, 1996).

Jong et al. (herein referred to as Jong) teaches a method of analysis of mRNA transcripts of the SMN gene in cells or normals, carriers and SMA patients. Jong teaches the SMN(T) was altered and responsible for SMA disease. Jong teaches analyzing the mRNA expression of the SMN gene offers a reliable technique for separating SMA patients, carriers and normal individuals (abstract). Jong teaches

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performing RT-PCR, like the instant claims, however used random primers rather than particular primers as required by the instant claims. Jong teaches then PCR-amplifying the single stranded cDNA using two pairs or primers to cover the SMN gene (page 148, col. 1). Jong teaches using biotin-labeled probes and detecting the probes with Luminescent Detection Kit (page 148, col. 2). Jong teaches determining the intensity of the RT-PCR products containing exon 7 or lacking exon 7 or B-actin with the Collage Image Analysis System to calculate the ratio of the products (page 149, col. 1). Jong then teaches a method to semi-quantitatively analyze the number of transcripts containing or lacking exon 7 by preparing a ratio between the RT-PCR products containing exon 7 and lacking exon 7 of normals, SMA patients and carriers. As seen in Figure 3, ratios of exon 7 containing fragments of SMA patients, carriers and normals was performed (page 151). A ratio is a quantitative method, as a value is obtained from the assay.

Jong does not specifically teach using specific primers of SEQ ID NO: 4 and SEQ ID NO: 5 for RT and does not specifically teach using a probe directed to the deletion region for detection of the presence or absence of the nucleic acid.

Lefebvre et al. (herein referred to as Lefebvre) teaches the absence of the SMN gene in SMA patients. Lefebvre teaches using SSCP analysis of amplified exons 7 and 8 in 229 SMA patients. Lefebvre teaches 213 or 229 SMA patience lacked the SMN exons 7 and 8 on both chromosomes as compared to 0 of 246 controls. Figure 5 illustrates the SSCP analysis of amplified exons 7 and 8.

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However, Powell teaches priming cDNA using a primer specific for the mRNA of interest. The specific primer can be located further 3' of the region to be amplified or may be the same as the 3' PCR primer. Powell teaches the advantages for using specific primers close to the site is that cDNA synthesis and subsequence amplification may be performed on less than intact preparations of total RNA.

Moreover, Gruber et al. (herein referred to as Gruber) teaches the desirability to use HUMEF1AB for positive internal controls. Gruber compares EF-1alpha as a positive control to b-actin as a positive control. Gruber teaches that detection of EF-1alpha mRNA is an appropriate internal standard. The advantages of EF-1 alpha as a universal positive control in nuclei acid detection assays would be its consistent expression in all living cells and its high evolutionary conservation between species. While Jong teaches using B-actin, substituting an equivalent positive control. The art teaches that positive controls are desirable, therefore, the ordinary artisan would have been motivated to have used any positive control desirable. The art teaches the benefits of using HUMEF1AB over b-actin, as it is more homogenous expression then did b-actin. The use of HUMEF1AB was within the prior art and the ordinary artisan would have been motivated to have used a positive control which is more homogenous than the positive control cited by Jong.

Additionally, Feuerstein teaches preferable methods of detection involves hybridization of a nucleic acid probe with a nucleic acid found in the deletions (col. 2, lines 65-68). Feuerstein teaches that the probes may be differentially labeled so that they may be distinguished (col. 3,lines 18-20). Probes bearing fluorescent labels are

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preferred with direct-labeled probes being most preferred (col. 3, lines 20-21).

Feuerstein teaches assaying for the presence or absence of the probe, one can detect the presence or absence of the target. Feuerstein specifically teaches that well known methods for detecting the presence or absence of deletions include hybridization with probes that are specific to nucleic acid sequences within the deleted regions, and detection of single strand conformation polymorphisms (SSCP) (col. 6, lines 55-68). Finally, detection and quantification of the hybridization complex formed between the probe and the sample nucleic acid indicates the presence or amount of the deletion nucleic acid sequence (col. 7, lines 55-60). Feuerstein teaches that the nucleic acid probes may be labeled using fluorescent dyes or enzymes (as commonly used in an ELISA) (col. 13, lines 40-45).

Bruce et al. (herein referred to as Bruce) teaches methods of analyzing PCR products quantitatively using PhosphorImagers, autoradiographic films and confirmed by sequencer. Bruce teaches that PCR products may be resolved by electrophoresis on gels. The gels are then dried and quantitated with a phosphorImager. Bruce also teaches that autoradiographic films of the gels were also quantitated with a BioImager. The identities of the amplified cDNAs were confirmed on an automated sequencer (page 231). Thus Bruce teaches the use of quantitative methods for determining the amount of cDNA on a gel or film.

Moreover, Lefebvre teaches the survival motor neuron (SMN) gene exons 7 and 8. SEQ ID NO: 1 of the instant application is 100% identical to positions 211-262 of the sequence of Lefebvre. However, Lefebvre teaches that exon 7 is positions 209-262.

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Moreover, SEQ ID NO: 2 of the instant application is 100% identical with potions 707-761 of the sequence of Lefebvre. However, Lefebvre teaches exon 8 is positions 707-1266.

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified the method of detecting the presence or absence of exons 7 and 8 of the SMN gene using the method of Jong by modifying the method to use probes as taught by Feuerstein in view of Bruce, Powell and Lefebvre. The method of Jong is described as a quantitation of the RT-PCR products of normal subjects, SMA patients and carriers (page 148, col 2). Jong teaches semi-quantitatively analyzing the numbers of transcripts containing or lacking exon 7. As noted in the response of May 26, 2004, Jong teaches using random primers in the RT process. The ordinary artisan would have been motivated to have modified the random RT primer with specific primers to the region of interest for the benefit taught by Powell in the art. Powell teaches the advantages for using specific primers close to the site is that cDNA synthesis and subsequence amplification may be performed on less than intact preparations of total RNA. Therefore the ordinary artisan would have been motivated to have used specific primers the SMN gene and HUMEF1AB, rather than random primers, to reverse transcribe the region of interest. Further following specific RT, the ordinary artisan would have been motivated to have performed PCR on the obtained fragments. Both Jong and Lefebvre teach the importance of exon 7 and 8 in the diagnosis of SMA. Therefore, amplifying using any primers which amplify exon 7 and 8 would function equivalently for determining the presence of the regions. The primers

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used in the instant application are specific to exon 7 and exon 8. The ordinary artisan would have been motivated to have used any primers which amplified exon 7 and exon 8 to obtain a PCR product which may be detected to determine the presence or absence of the amplicon. By amplifying the two exons independently, provides valuable information of the presence of the individual exons. Therefore, the ordinary artisan would have been motivated to use any of the equivalent primers for amplifying the well known SMN gene taught in the art. Designing primers and probes were well within the skill of the ordinary artisan and routine optimization would yield equivalent results. Additionally, once the amplicons were formed, the ordinary artisan would have recognized that nucleic acids may be detected by numerous methods in the art. The art teaches quantitative PCR, SSCP, probing in regions of deletion etc for quantitating nucleic acid. Jong teaches performing quantitative analysis by determining the ratio of exon 7 containing fragments and exon 7 deficient fragments. As seen in Figure 3 of Jong (page 151), SMA patients, carriers and normals have varying ratios. The ordinary artisan would have recognized that, at the time the invention was made, exon deletions could be accurately and quantitatively detected using probes to the deleted exons. Feuerstein specifically teaches that at the time the invention was made, that the detection using probes to deleted regions and detection with SSCP were equivalent methods for detecting deletions. Thus, the skilled artisan would have been motivated to have detected the absence of exons 7 and 8 in individuals to determine the SMA status. Since the art teaches that deletions of exons 7 and 8 are found only in SMA patients, detection of the deletions would provide an accurate means of detecting whether an

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individuals was at risk or had SMA. Finally, the art teaches that BioImagers and OD are well accepted tools in the art for measuring quantity of nucleic acid in a sample. The ordinary artisan would have been motivated to have quantitated the nucleic acid in patients, carriers and controls because it is clear from the art that the absence of exon7 and/or 8 is associated with disease phenotype. The quantification of the nucleic acid

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patients, carriers and controls because it is clear from the art that the absence of exon7 and/or 8 is associated with disease phenotype. The quantification of the nucleic acid provides a more accurate means for obtaining results. Thus, the ordinary artisan would have been motivated to have improved the semi-quantitative method of Jong with a more quantitative method such as using a Biolmager or OD for detection of the precise amount of nucleic acid in a sample. The state of the art for methods of detecting and quantifying nucleic acids in disease detection where particular mutations or variations are known is very high. The ordinary artisan, given teaches of a particular mutation and its association with a particular disease would be motivated to have detection and quantified the nucleic acid using any of the variety of well known techniques for detection and quantification. The instant application appears to take a well known

disease and a well known mutation and detect and quantify using well known detection

and quantification means. This combination of prior methods does not constitute an

unobvious contribution over the art.

Conclusion

- 13. No claim allowable.
- 14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeanine Goldberg

Patent Examiner

June 3, 2004